

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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BRAINTREE LABORATORIES, INC. : Civ. Action No.: 14-cv-8147 (AJN)
[rel. 12-cv-6851-AJN]
:
Plaintiff, : ECF Case
:
v. : ANSWER
:
TARO PHARMACEUTICALS USA, INC., TARO :
PHARMACEUTICAL INDUSTRIES, LTD. :
:
Defendants. :
:
----- X

Defendants Taro Pharmaceuticals USA, Inc. (“Taro USA”) and Taro Pharmaceutical Industries, Ltd. (“TPI”) (together “Defendants”) answer the Complaint by Braintree Laboratories, Inc. (“Braintree” or “Plaintiff”) as follows:

NATURE OF THE ACTION

1. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that Plaintiff’s claims purport to arise under 35 U.S.C. §§ 271 and 281 and that Defendants filed ANDA No. 206431 with the FDA, which speaks for itself and the Court is respectfully referred to this application for its contents.

Defendants deny the remaining allegations contained in this paragraph.

PARTIES

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph and therefore deny same.

3. Defendants admit the allegations contained in this paragraph.

4. Defendants admit the allegations contained in this paragraph.

5. Defendants state that following any FDA approval of ANDA No. 206431, Defendants may make, use, offer to sell and/or sell generic products that are the subject of ANDA No. 206431 throughout the United States and/or import such generic products into the United States.

JURISDICTION AND VENUE

6. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that this Court has subject matter jurisdiction over this action.

7. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, Defendants state that they will not contest personal jurisdiction in this case.

8. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, Defendants state that they will not contest personal jurisdiction in this case.

9. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny that the Court has personal jurisdiction over TPI. Nevertheless, only for the purpose of this action, TPI will not contest personal jurisdiction in this case.

10. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants state that if the FDA approves ADNA No. 206431, Defendants deny they will develop or manufacture the generic version of Braintree's SUPREP® drug product described in ANDA No. 206431. Defendants admit that if approved, they may market and/or sell within the United States the generic version of Braintree's SUPREP® drug

product described in ANDA No. 206431. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore deny same.

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Braintree's sales contained in this paragraph and therefore deny same. Defendants deny the remaining allegations of this paragraph.

12. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that TPI was a party to the actions referred to in this paragraph, respectfully refer the Court to the dockets of those actions for the filings referred to in this paragraph and deny that any position taken by TPI in either action has any effect on the Court's lack of personal jurisdiction over TPI in this action. Defendants deny the remaining allegations contained in this paragraph.

BACKGROUND

13. Defendants admit that SUPREP is a sodium sulfate, potassium sulfate and magnesium sulfate osmotic laxative. With respect to the remaining allegations of this paragraph, Defendants deny the allegations to the extent that they conflict with the information set forth in the FDA's records relating to NDA No. 22372 for SUPREP Bowel Prep Kit. Except as expressly admitted above, Defendants deny the allegations of this paragraph.

14. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit only that the '149 patent is listed in the Orange Book in connection with SUPREP. Defendants deny the remaining allegations of this paragraph.

THE '149 PATENT

15. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, the '149 patent and its reexamination certificate speak for themselves and the Court is respectfully referred to those documents for their terms. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the history of the '149 patent and its reexamination and therefore deny same. Defendants deny that the '149 patent was duly and legally issued by the USPTO. Defendants deny the remaining allegations contained in this paragraph.

16. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, the '149 patent speaks for itself and the Court is respectfully referred to the '149 patent for its claims. Defendants otherwise deny the allegations contained in this paragraph.

17. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph and therefore deny same.

18. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny that the owner of the '149 patent has any right to sue for infringement; Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in this paragraph and therefore deny same.

INFRINGEMENT BY TARO USA AND TPI

19. Defendants admit that they notified Braintree by letter dated September 2, 2014 that Taro Pharmaceuticals U.S.A. Inc. as U.S. Agent for Taro Pharmaceutical Industries Ltd. had submitted ANDA No. 206431 to the FDA per Section 505(j) of the Federal Food, Drug and Cosmetic Act and that this ANDA listed SUPREP as the reference listed drug. The Taro Notice Letter speaks for itself and the Court is respectfully referred to this document for its content.

20. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that they seek approval of a Magnesium Sulfate Anhydrous, Potassium Sulfate and Sodium Sulfate oral solution products that lists SUPREP as the reference listed drug. As to the remaining allegations, ANDA No. 206431 speaks for itself and the Court is respectfully referred to this document for its content.

21. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations contained in this paragraph.

22. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations contained in this paragraph.

23. Defendants admit the allegations contained in this paragraph.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY TARO USA AND TPI)

24. Defendants reassert and reallege each of their responses to the preceding paragraphs of the Complaint as if fully set forth here.

25. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations contained in this paragraph.

26. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit only that they had knowledge of the '149

patent when they filed ANDA No. 206431, and Defendants deny the remaining allegations contained in this paragraph.

27. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations contained in this paragraph.

28. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations contained in this paragraph.

29. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegation contained in this paragraph.

30. This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations contained in this paragraph.

RESPONSE TO REQUEST FOR RELIEF

In response to the unnumbered **WHEREFORE** paragraph, Defendants deny that Plaintiff is entitled to recover any damages from Defendants or to any other form of relief from Defendants.

GENERAL DENIAL

To the extent not specifically admitted above, including (but not limited to) every instance where Defendants are without knowledge or information sufficient to form a belief about the truth of the allegations, Defendants deny all allegations of the Complaint, including all headings to the extent the headings may be deemed allegations. Further, in each instance where the Defendants refer to referenced documents for a description of their content, Defendants deny the allegations to the extent they are inconsistent with those documents.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The '149 patent is invalid for failing to meet the requirements of patentability, including without limitation, under 35 U.S.C. §§ 101, 102, 103, 111, 112, 116, 132, 135, 282, 287, for improper double patenting and/or for any other judicially created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE

Defendants do not infringe and will not infringe any valid claim of the '149 patent either literally, under the doctrine of equivalents, directly, indirectly, willfully or otherwise.

THIRD AFFIRMATIVE DEFENSE

The doctrine of prosecution history estoppel (by argument or amendment) and disclaimer preclude any finding of infringement of certain claims of the '149 patent.

Defendants reserve their right to assert any other defense or counterclaims that are revealed in discovery.

WHEREFORE, Defendants request that the Complaint be dismissed with prejudice and that Defendants be awarded the costs of this action, their attorneys' fees, and all other relief that this Court deems just and proper.

Dated: New York, New York
January 12, 2014

Respectfully submitted,

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